

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of Claims:

1. (Currently amended) A transdermal drug delivery composition comprising consisting essentially of:

(a) a copolymer comprising

(i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and

(ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; and, optionally,

(c) a component selected from the group consisting of delivery enhancing adjuvants, tackifiers, plasticizers, and combinations thereof,

wherein the composition is free of undissolved fentanyl.

2. (Original) The composition of claim 1 wherein the A monomer is selected from the group consisting of isoctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate.

3. (Original) The composition of claim 1 wherein the A monomer is isoctyl acrylate.

4. (Original) The composition of claim 1 wherein the B monomer is selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N,N-

diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof.

5. (Original) The composition of claim 1 wherein the B monomer is 2-hydroxyethyl acrylate.

6. (Original) The composition of claim 5 wherein the copolymer comprises from about 5% to about 45% of 2-hydroxyethyl acrylate by weight based on the total weight of all monomers in the copolymer.

7. (Original) The composition of claim 1 wherein the copolymer further comprises a macromonomer.

8. (Original) The composition of claim 7 wherein the macromonomer is a functionally terminated polymethylmethacrylate.

9. (Original) The composition of claim 7 wherein the copolymer contains from about 1% to about 6% of macromonomer by weight based on the total weight of all monomers in the copolymer.

10-15. (Canceled).

16. (Original) The composition of claim 1 wherein the concentration of fentanyl in said transdermal drug delivery composition is from about 12% to about 24% by weight.

17. (Original) The composition of claim 7 wherein the copolymer comprises from about 50 to about 94% isooctyl acrylate, about 5% to about 40% 2-hydroxyethyl acrylate, about 1% to about 6% macromonomer, and 0% to about 20% vinyl acetate by weight.

18. (Original) The composition of claim 7 wherein the copolymer comprises from about 52% to about 60% isooctyl acrylate, about 35% to about 40% 2-hydroxyethyl acrylate, about 1% to about 4% macromonomer, and 0% to about 10% vinyl acetate by weight.

19-27. (Canceled).

28. (Original) A method of treating in a mammal a condition capable of treatment by fentanyl comprising the steps of:

- (a) providing a composition according to claim 1;
- (b) placing the composition on the skin of a mammal; and
- (c) allowing the composition to remain on the skin for a time sufficient to establish or maintain a therapeutically effective blood level of fentanyl in the mammal.

29. (Original) A method of providing analgesia to a mammal comprising the steps of:

- (a) providing a composition according to claim 1;
- (b) placing the composition on the skin of a mammal; and
- (c) placing the composition to remain on the skin for a time sufficient to establish or maintain an analgesically effective blood level of fentanyl in the mammal.

30-34. (Canceled).

35. (Currently amended) A transdermal drug delivery composition comprising consisting essentially of:

- (a) a copolymer comprising:
 - (i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and
 - (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; wherein the B monomers are selected from the group consisting of 2-hydroxyethyl

acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N,N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; and, optionally,

(c) a component selected from the group consisting of delivery enhancing adjuvants, tackifiers, plasticizers, and combinations thereof,

wherein the composition is free of undissolved fentanyl.

36. (Currently amended) A transdermal drug delivery composition ~~comprising~~ consisting essentially of:

(a) a copolymer comprising:

(i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and

(ii) about 5% to about 45% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; wherein the B monomers are selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, glyceryl acrylate, N,N-diethylacrylamide, 2-ethoxyethoxyethyl acrylate, 2-ethoxyethyl acrylate, tetrahydrofurfuryl acrylate, acrylic acid, acrylamide, vinyl acetate, N-vinyl pyrrolidone and mixtures thereof; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; and, optionally,

(c) a component selected from the group consisting of delivery enhancing adjuvants, tackifiers, plasticizers, and combinations thereof,

wherein the composition is free of undissolved fentanyl.

37-38. (Canceled).

39. (Currently amended). The composition of claim 1 wherein the composition ~~further comprises~~ contains a delivery enhancing adjuvant.

40. (Previously presented). The composition of claim 39 wherein the delivery enhancing adjuvant is selected from the group consisting of alkane polyols, fatty acids, fatty acid esters, fatty alcohols, terpenes, C₅-C₁₈ alkyl esters of a carboxylic acid, and mixtures thereof.

41. (Previously presented). The composition of claim 39 wherein the delivery enhancing adjuvant is selected from the group consisting of ethyl oleate, isopropyl myristate, glycerol, tetraglycol, methyl laurate, N,N-dimethyldodecylamine N-oxide, limonene, terpineol, tetraethylene glycol, menthol, and mixtures thereof.

42. (Previously presented). The composition of claim 39 wherein the concentration of the delivery enhancing adjuvant is from about 5% to about 40% by weight based on the total weight of the composition.

43. (Currently amended). The composition of claim 39 wherein the ~~skin permeation enhancer~~ delivery enhancing adjuvant is tetraglycol.

44. (Currently amended). The composition of claim 39 wherein the ~~skin permeation enhancer~~ delivery enhancing adjuvant is methyl laurate.

45. (Currently amended). The composition of claim 17 wherein the concentration of fentanyl is from about 12% to about 22% by weight, and wherein the composition ~~further comprises~~ contains about 15% to about 35% by weight of a ~~permeation enhancer~~ delivery enhancing adjuvant selected from the group consisting of methyl laurate, tetraglycol, and mixtures thereof.

46. (Previously presented). The composition of claim 45 wherein the concentration of fentanyl is from about 12% to about 17% by weight and the concentration of methyl laurate is from about 20% to about 35% by weight.

47. (Previously presented). The composition of claim 45 wherein the concentration of fentanyl is from about 15% to about 22% by weight and the concentration of tetraglycol is from about 15% to about 25% by weight.

48-51. (Withdrawn).

52. (Previously presented). A device for the transdermal delivery of fentanyl comprising a backing and a composition according to claim 1, said composition being adhered to one surface of the backing.

53. (Previously presented). The composition of claim 39 wherein the delivery enhancing adjuvant is a skin permeation enhancer.

54. (Currently amended). A transdermal drug delivery composition comprising consisting essentially of:

- (a) a copolymer comprising
 - (i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexyl acrylate; and
 - (ii) about 5% to about 45% of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; wherein at least one B monomer is 2-hydroxyethyl acrylate; and
- (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; and

(c) a delivery enhancing adjuvant selected from the group consisting of methyl laurate, tetraglycol, and mixtures thereof;
wherein the composition is substantially free of undissolved fentanyl.

55-91. (Withdrawn).

92. (Currently amended) A ~~device for the transdermal drug delivery of fentanyl comprising a backing and a pressure sensitive adhesive composition adhered to one surface of the backing, the composition comprising~~ consisting essentially of:

- (a) a copolymer comprising
 - (i) one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group; and
 - (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; and
- (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is free of undissolved fentanyl.

93. (Currently amended) A device according to claim 92, wherein the ~~composition comprises about 8% fentanyl based on the total weight of the composition~~ concentration of fentanyl in said composition is about 8% by weight.

94. (New) A device for the transdermal delivery of fentanyl comprising a backing and a composition according to claim 92, said composition being adhered to one surface of the backing.

95. (New) A transdermal drug delivery composition consisting essentially of:

(a) a copolymer of:

- (i) one or more A monomers selected from the group consisting of isooctyl acrylate, 2-ethylhexyl acrylate, butyl acrylate, and cyclohexylacrylate; and
- (ii) one or more ethylenically unsaturated B monomers copolymerizable with the A monomer, wherein the B monomers are selected from the group consisting of 2-hydroxyethyl acrylate, 2-hydroxymethacrylate, vinyl acetate, glycidyl methacrylate, and mixtures thereof; and

(b) about 8% to about 30% by weight fentanyl based on the total weight of the composition;

wherein the composition is free of undissolved fentanyl.

96. (New) A composition according to claim 95, wherein the concentration of fentanyl in said composition is about 8% by weight.

97. (New) A device for the transdermal delivery of fentanyl comprising a backing and a composition according to claim 95, said composition being adhered to one surface of the backing.

98. (New) A transdermal drug delivery composition consisting essentially of:

(a) a copolymer comprising

- (i) about 40 to about 95% by weight of one or more A monomers selected from the group consisting of alkyl acrylates containing 4 to 12 carbon atoms in the alkyl group and alkyl methacrylates containing 4 to 12 carbon atoms in the alkyl group;

- (ii) about 5 to about 55% by weight of one or more ethylenically unsaturated B monomers copolymerizable with the A monomer; and

- (iii) 0 to about 20% by weight of one or more macromonomers copolymerizable with the A and B monomers;

- (b) about 8% to about 30% by weight fentanyl based on the total weight of the composition; and, optionally,

(c) a component selected from the group consisting of delivery enhancing adjuvants, tackifiers, plasticizers, and combinations thereof,
wherein the composition is free of undissolved fentanyl.

99. (New) A composition according to claim 98, wherein the concentration of fentanyl in said composition is about 8% by weight.

100. (New) A composition according to claim 98, wherein the copolymer contains from about 1% to about 6% of the macromonomer by weight based on the total weight of all monomers in the copolymer.

101. (New) A composition according to claim 98, wherein the composition includes a delivery enhancing adjuvant.

102. (New) A composition according to claim 101, wherein the delivery enhancing adjuvant is selected from the group consisting of methyl laurate, isopropyl myristate, and mixtures thereof.

103. (New) A device for the transdermal delivery of fentanyl comprising a backing and a composition according to claim 98, said composition being adhered to one surface of the backing.